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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
10/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	09/367,950	EKSTROM, TOMMY	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/3/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-36,38 and 42-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-36,38 and 42-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/2008;9/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 3, 2008 has been received and entered into the application.

Action Summary

The rejection of claims 13-36, 38, 42 and 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claims 13-36, 38, 42 and 43 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is being **maintained** for the reasons stated in the previous Office Action. However, the rejection is modified in this Office Action to address the newly added limitations.

The rejection of claims 13-15, 17, 18, 20-36, 38, 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over Carling of record is being **maintained** for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed June 3, 2008 have been fully considered but they are not persuasive.

With regard to 35 U.S.C. 101 rejection, Applicants argue that the Office action takes the position that claim 13 is directed to "the manipulation of an abstract idea" which is not the same thing as claiming an abstract idea per se, and there is no prohibition in U.S. law to claiming a method of "manipulating" and abstract idea. This is not found to be persuasive because the rejection was made based on the Board's remand August 28, 2007 (see page 10 of the remand). It is noted that newly amended claim 13, requires 1) "providing" an inhaler to the patient and 2) "providing a recommendation" to the patient to inhale the composition from the inhaler on an as-needed basis, as determined by the patient based on the patient's symptoms, as a treatment and preventive measure, "when" the patient experiences an increase in asthma symptoms. Therefore, what happens after the patient is recommended to inhale the composition is not an element of the claim. There is no requirement a practical application actually be associated with this "recommendation". "[a] process is … an act, or a series of acts, performed upon the subject matter to be ***transformed*** *and* ***reduced*** to a different state or thing." In re Schrader, 22 F.3d 290, 293-94, 30 USPQ2d 1455, 1459 (Fed. Cir. 1994), citation omitted. (See also State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F3d 1368, 1373, 47 USPQ2d 1596, 1601 (Fed. Cir. 1998) holding that a claimed system was statutory subject matter because it produced "a useful, concrete and tangible result."). In this case, neither a

transformation nor reduction would result from the claimed invention because the limitation that the patient actually performs the administration of the claimed composition is not an element of the claim. The "reduction" or "transformation" would only occur with the actual administration of the claimed combination. Thus, no reduction or transformation would take place with the claimed invention because the claims do not recite the necessary step of a practical application associated with the claimed recommendation. That is, a recommendation for action does not guarantee that the required step be taken which would achieve the "reduction" or "transformation" in the process claims.

With regard to 35 U.S.C. 103(a) rejection, Applicants argue that **claim 13** requires that the recommendation to be inhale the composition **on as-needed bases, as** determined by the patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms. Independent **claim 35** requires that the recommendation to be inhale the composition **on an as-needed basis, as determined by the patient** based on the patients' symptoms, as a complement to maintenance treatment of patient's asthma. Independent **claim 36** requires that the recommendation be to inhale the composition on **an as-needed basis, as determined by the patient,** when the patient is expecting to encounter as asthma triggering event, as a preventative measure. Independent **claim 42** requires that the recommendation to be inhale a maintenance dose of the composition from the inhaler and, if the patient experiences acute asthma symptoms, to inhale additional doses **as needed for symptomatic relief**. And finally, independent

claim 43 is drawn to a method of "reducing the incidence of acute asthma attacks in a patient" by providing the inhaler and a recommendation to the patient to inhale the composition from the inhaler **on an as-needed basis, as determined by the patient** based on the patient's symptoms, as a treatment and to reduce the incidence of acute asthma attacks, when the patient experiences an increase in asthma symptoms. Therefore, the claims differ in the details of the recommendation provided to the patient as set forth above and the cited reference, Carling et al. (WO93/11773), which teaches the combination of formoterol and budesonide in a single inhaler to be used **twice a daily dosing regimen as a basic treatment of asthma**, particularly nocturnal asthma. This is not found to be persuasive because the claims in the instant Application and the teachings in the Carling et al. would have been obvious variations of the other to one of ordinary skill in the art. One of ordinary skill in the art would be motivated and found it obvious to combine the method of Carling et al. and administering the method on as needed basis for rescue purposes, as determined by the patient in any of the circumstanced detailed in claims 13, 35, 36, 42 and 43 because Carling et al. teach that the dosages strongly depends on the severity of disease, whether mild, moderate, or severe asthma (see page 6, lines 27-29), and the suitable daily dosage is up to 8 inhalation (see page 7-9). One of ordinary skill in the art would be motivated to recommend the patient to employ Carling et al's composition in as needed bases when the patent experiences an increase in asthma symptoms knowing the safe, effective and maximum dosages taught by Carling et al. Applicants' attention is drawn to the teaching of Carling et al. on page 7-9, exemplified amounts of active agents **per dose** of

inhalation, and the **maximum dosage** of the each of the active agents taught in page 6, lines 21-30, which calculate up to 8 inhalation per day without going over the maximum daily dosage (For example: suitable **daily dosage** of formoterol is 6-100ug on page 6 lines 21-25 and in Example 1 on page 7, contains 12ug formoterol **per dose** which would equal to 8.3 doses/day to be exact; for the suitable **daily dosage** of budesonide on page 6 lines 21-25 with a preferred dose up to 1600ug and in Example 1 contains 200ug **per dose** of budesonide would give 8 doses maximum). It is noted that similar calculation is made by the Applicants using **a maximum daily dose** of each of the active agents in the instant specification, page 8 Example 5, **"36/640ug (8puffs of 4.5/80ug) and 36/1280ug (8 puffs of 4.5/160ug)"**. There is a reasonable expectation of recommending patients to administer the Carling's composition as needed bases because Carling et al. teaches the dosage of the combination extending twice a day (2 inhalations) up to 8 inhalations a day.

Applicants argue that use of that short-acting bronchodilator is left to the discretion of the patient, in contrast, use of budesonide or other powerful glucocorticoids is not, or at least wasn't until the present invention. This is not found to be persuasive because Carling et al. teach otherwise. Carling et al. teach that the combination of budesonide with formoterol can be administered effectively and safely up to 6-100ug formoterol with a daily dose of budesonide in a range of 50-4800ug. (see page 6 lines 24 and 26).

Applicants argue that the Carling et al. reference itself actually says nothing about the number of inhalations per administration, rather only that those inhalations

should be group into just two administrations per day ("the intended dose regimen is a twice daily administration" on page 6, lines 22-23). This is not found to be persuasive because one of ordinary skill in the art would immediately recognize that up to 8 inhalation can be administered in a daily bases. Applicants' attention is drawn to the teaching of Carling et al. on page 7-9, exemplified amounts of active agents **per dose** of inhalation, and the **maximum dosage** of the each of the active agents taught in page 6, lines 21-30, which calculate up to 8 inhalation per day without going over the maximum daily dosage (For example: suitable **daily dosage** of formoterol is 6-100ug on page 6 lines 21-25 and in Example 1 on page 7, contains 12ug formoterol **per dose** which would equal to 8.3 doses/day to be exact; for the suitable **daily dosage** of budesonide on page 6 lines 21-25 with a preferred dose up to 1600ug and in Example 1 contains 200ug **per dose** of budesonide would give 8 doses maximum). It is noted that similar calculation is made by the Applicants using **a maximum daily dose** of each of the active agents in the instant specification, page 8 Example 5, **"36/640ug (8puffs of 4.5/80ug) and 36/1280ug (8 puffs of 4.5/160ug)"**.

Applicants argue that the exhibits A-F submitted on June 29, 2005 and March 3, 2006, show that from a date prior to the present priority date to as late as 2003, glucocorticosteroid-containing therapeutics were routinely prescribed for fixed-dosage use twice per day as maintenance therapy, with the patient forbidden to vary daily dosage outside that regimen, whether "on demand" "as needed" or for any other reason; Once one understand how inhaled glucocorticosteroids such as budesonide were typically prescribed for asthma patients prior to Applicant's invention, it is apparent that

Applicants interpretation of Carling et al. is the one that a person of ordinary skill would have taken from this reference. This is not found persuasive because the teachings of Carling et al. are clear as to the specific combination comprising formoterol and budesonide useful in the specific medical treatment, namely, asthma. This specific teaching would have motivated one of ordinary skill in the art to make a protocol for a patient having symptoms of asthmatic attack which include self-administration of a dose as needed up to the maximum taught by Carling et al. One of ordinary skill in the art would recommend the dosage regimen taught by Carling et al. to an asthmatic patient in order for such a patient to safely rescue from an asthmatic attack. One of ordinary skill would recognize that it is advantageous for the patient to self-administer the treatment to avoid the dire consequences of waiting for professional assistance. Therefore, one of ordinary skill in the art would recommend that those patients, currently using the specific Carling et al combination of formoterol and budesonide for maintenance therapy, use the combination during an asthmatic attack at a dose up to the limit recommended by Carling et al for such an emergency.

Applicants argue that the glucocorticosteroid budesonide is the sole active ingredient in an inhaler sold under the trademark Plumicort® Turbuhaler® for maintenance treatment of asthma and there is no provision for additional doses to be taken “as needed”. This is not found to be persuasive because the issue is the combination therapy comprising budesonide and formoterol not budesonide alone; and the specific teaching of the combination from the minimum dose and the maximum dosages are well taught by the Carling et al. As anyone of ordinary skill in the art will

appreciate, preferred dosages and frequencies e.g. twice a day, are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely severe asthmatic patient or one having an unusually frequent asthmatic attack or episodes would require a correspondingly higher dosage or frequent dosages.

Applicants argue that Exhibit B (a product insert of Symbicort Turbuhaler), disclose Symbicort Turbuhaler, a budesonide/formoterol inhalation powder product similar to that disclosed by Carling et al. says that the “recommended dosage” is 1-2 inhalations twice daily; and that physician can choose to reduce the number of inhalations to one daily; but there is nothing in the document recommending that the patient inhale the product "as needed". This is not found to be persuasive because again, Carling et al's teaches the same combination comprising budesonide and formoterol with ranges of dosages allows up to 8 inhalation per day.

Applicants argue that Exhibit C, emphasizes repeatedly that the product must be used neither more nor less often than instructed by the physician and that the patient is adamantly instructed not to use the combination therapy more frequently than 2 times daily, spaced approximately 12 hours apart, and told to inhale only the recommended dose of 1 inhalation each time. This is not found to be persuasive because Exhibit C concerns with different combination of active agents such as fluticasone/salmeterol, not instantly claimed active agents.

Applicants argue that Exhibit D and E teaches that Barnes' objective characterization of Appellant's treatment as "remarkable" and the results as "surprisingly

good" certainly qualifies as strong evidence of nonobviousness. This is not found to be persuasive because the instantly claimed method is deemed obvious in view of the teachings of Carling et al. who teaches the composition comprising the same active agent for the same purpose with varying ranges of dosages. Carling et al. teaches that combination of the two active agents have greater efficiency and duration of bronchodilator action, and rapid onset of action, which provides rescue medicine, adequate dosing for the treating asthma (see page 4, lines 4-21).

Applicants argue that the Carling et al's reference to "severity of disease" as being one of the bases for setting the amount of the twice-daily doses of the composition does not mean that the patient should be told to take more doses if his/her disease is particularly severe on a given day and it simply means that the overall level of the patient's disease is one of the factors and that the prescribing physician should take into account in setting the twice-daily dose. This is not found to be persuasive because Carling et al. not only teaches twice a day dosing but they teach that the dosage adjustment which depends strongly on the patient (age, weight etc), severity of disease (mild, moderate, severe asthma etc..) See page 6, lines 27-29. It is noted that this teaching of Carling et al. should not be ignored and that the prescribing physician should take this teaching into account as well.

Applicants argue that Carling et al. teaches a fixed, twice-daily dose (there being no allowance in Carling et al. for anything other than a fixed, twice daily dose), the same would be true of any additional dose taken each day. This is not found to be persuasive because Carling et al. teaching clearly states the minimum and maximum daily dosages

and dosage per inhalation. Additionally, Carling et al. teaches the dosage adjustments are strongly needed depends on particular patients (age, weight etc), severity of disease (mild, moderate, severe asthma etc..) being treated. The prescribing physician would/should consider all the options including dosage options taught by Carling et al. that would benefit his asthmatic patient to be treated.

Applicants argue that the paradigm for use of budesonide-containing products dictated fixed dosage use for maintenance therapy, not potentially variable dosage as determined by day-to-day by the patient for relief of an acute attack or when the patient expects to encounter as asthma-triggering event. This is not found to be persuasive because again, the issue is the specific combination comprising budesonide and formoterol for the treatment of asthma. It is the Examiner's position the claimed invention as a whole would have been obvious to one of ordinary skill in the art in view of Carling et al's teaching. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrases **"**the recommendation causes the patient to inhale the composition **at least one occasion"** lack literal support in the specification as originally filed.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. In this case, Applicants has not conveyed possession of the invention with reasonable clarity to one skilled in the art.

Claims 49-53 recite the phrases **"**the recommendation causes the patient to inhale the composition **at least one occasion"**. Claims are read in light of the Specification and although the phrases of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty.

There is no support for the recommendation causing the patient to inhale the composition on "**at least one** occasion" administration in the specification as filed. Therefore, there is lack of written description of the limitation of "causing.....**at least one** occasion" as instantly claimed.

The premise for the limitation of "the recommendation causes patient to inhale the composition on at **least one** occasion" appears to be derived from the disclosure in

the instant specification on page 8, Example 5 that a patient on maintenance treatment with the fixed combination of formoterol/budesonide in a dose **bid (twice a day)** additionally uses the same combination either for rescue purposes **once or twice a daily** to treat sporadic breakthrough symptoms, or **as needed** to treat exacerbations during one or two weeks. The term "as needed" described by Applicants encompasses not only the medical "need" determined by the patient but reads on the circumstances where there is **no "need"** of administration of the claimed composition. The specification does not however, indicate why one should assume based on this example comprising the specific frequency "once or twice a day" or "as needed" would necessary encompass the limitation of "at least one".

Therefore, one of skill in the art would reasonably have concluded Applicants were not in possession of the claimed invention of what is considered as a next additional step beyond what is originally described in the instant specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-36, 38, 42 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 13, 42 and 43 require steps to "providing" a patient as inhaler and "provide" a recommendation to use the inhaler .."if" or "when" the patient experiences acute asthma symptoms. It is noted that a process is an act or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing.

Therefore, what happens after the providing steps, the actual administration of the inhaler to patient's body is not an element of the claim. There is no requirement a practical application actually be associated with this provided steps. "[a] process is … an act, or a series of acts, performed upon the subject matter to be *transformed and reduced* to a different state or thing." In re Schrader, 22 F.3d 290, 293-94, 30 USPQ2d 1455, 1459 (Fed. Cir. 1994), citation omitted. (See also State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F3d 1368, 1373, 47 USPQ2d 1596, 1601 (Fed. Cir. 1998) holding that a claimed system was statutory subject matter because it produced "a useful, concrete and tangible result."). In this case, neither a transformation nor reduction would result from the claimed invention because the limitation that the patient actually performs the administration of the claimed composition is not an element of the claim. The "reduction" or "transformation" would only occur with the actual administration of the claimed combination. Thus, no reduction or transformation would take place with the claimed invention because the claims do not recite the necessary step of a practical application associated with the claimed recommendation. That is, a recommendation for action does not guarantee

that the required step be taken which would achieve the claimed "reduction" or "transformation". Therefore, the claimed subject matter is deemed non-statutory.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13-15, 17, 18, 20-36, 38 and 42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling of record.

Carling et al. on page 6, lines 5-30, teach the suitable daily asthmatic dose of formoterol fumarate dihydrate as required by claim 15 and budesonide within Applicant's daily dosage of "on demand" (twice a day) and the dosages strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc..).

Carling et al. on pages 7-9 exemplify amounts of active agents per dose of inhalation, which calculate up to 8 inhalation per day without going over the maximum daily dosage.

Carling teaches at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising

Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but also a rapid onset of action.

The difference between Carling et al. and Applicant's invention is recommending a patient to use the inhaler as needed and when needed as determined by the patient based on the patient's symptoms, to provide short-term symptomatic relief of acute asthmatic symptoms set forth in claims 13 and 36, instructing patient to inhale additional doses as needed if he experiences asthma including acute asthmatic episode, a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, and the particle size set forth in claim 22 and recommendation resulting at least one use of the inhaler set forth in claims 49-53.

However, to recommend the patient to inhale, as needed, as determined by the patient's symptoms in acute asthmatic episode is obvious since Carling et al. teach that the dosages strongly depends on the severity of disease (mild, moderate, severe asthma) and the suitable daily dosage is up to 8 inhalation. One of ordinary skill in the art would be motivated to recommend those patient with severe asthma or acute asthmatic attack to use the Carling's composition as needed bases up to 8 inhalations as suggested by Carling et al. that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended by Carling et al. It is noted that combination of formoterol with budesonide is well known to be

beneficial for the treatment of asthma as taught by Carling et al. Moreover, if that patient experiencing acute asthmatic attack even with ongoing twice a day dosing regimen, he still can safely inhale additional 6 inhalations without going over the maximum suitable daily dosage in general asthmatic condition taught by Carling et al. to achieve its known therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to recommend that those patients, currently using the specific Carling et al combination of formoterol and budesonide for maintenance therapy, use the combination during an asthmatic attack at a dose up to the limit recommended by Carling et al for such an emergency. One of ordinary skill would recognize that it is advantageous for the patient to self-administer the treatment to avoid the dire consequences of waiting for professional assistance.

Further, patients disclosed by Carlings including those taking twice a day regimen (at least one occasion), e.g. two-times per day to prevent and treat asthma symptoms would be included in the range of "as needed as determined by the patient" because those patients may only “need” twice a day dosing per their medical condition.

The molar ratio of active agents to be used set forth in claim 14, the selection of carrier set forth in claims 23 and 24, and the particle size of active agents set forth in claim 22, are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, 20-36, 38, 42-50 above, and further in view of Aberg et al. (U.S.Patent 5,795,564) and Ryrfeldt et al. of record.

Carling et al. as applied as before.

Carling et al. do teach the isomer of formoterol set forth in claim 16 and the specified epimer of budesonide set forth in claim 19.

Aberg et al. teach (R, R) isomer of formoterol as required by claim 16 is a potent bronchodilator with reduced adverse effects in treatment of asthma. (abstract, column, 1, lines 25-35).

Ryrfeldt et al. teach that 22R epimer of budesonide is more potent in the treatment of bronchial asthma than 22S epimer.

However, it would have been obvious to one of ordinary skill in the art to employ (R, R) enantiomer of formoterol and 22 R epimer of budesonide in view of Aberg et al. and Ryrfeldt et al. because both of the references of Aberg and Ryrfeldt teach specific isomers form that possesses potent asthmatic effect of the active agents utilized in Carling reduced adverse effects in treatment of asthma. One would have been motivated to employ (R,R) isomer of formoterol and 22R epimer of budesonide in Carling's composition with reasonable expectation of successfully treating asthmatic patients with reduced adverse effects.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.0

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is

571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
September 30, 2008